MAY - 3 2001

Section II - Summary of Safety and Effectiveness

K003529

(1) Contact Information

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(2) Company Information

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Telephone: (949) 595-4770
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(3) Device Name

Sanarus Core Tissue Biopsy System

(4) Device Description

The Sanarus Core Tissue Biopsy System consists of a sticking probe, tissue cutter, control unit and specimen container. The sticking probe is operated by the control unit and utilizes cold temperatures at its tip to engage the tissue to be sampled. The tissue cutter is coaxially mounted around the sticking probe and is used to core the tissue specimen. The tissue cutter will be available in several gauge sizes and lengths.

(5) Indications for Use

The device is indicated for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

The device is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality

is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

(6) Name of Predicate or Legally Marketed Device

Bard® Monopty® Disposable Biopsy Instrument
Mammotome® Hand Held System
Mammotome® Hand Held 8 Gauge Probe

(7) Substantial Equivalence

The Sanarus Core Tissue Biopsy System is substantially equivalent to the Bard® Monopty® Disposable Biopsy Instrument that was determined to be substantially equivalent on February 16, 1993 (reference K922939). The Sanarus system is also substantially equivalent to the Mammotome® Hand Held System that was determined to be substantially equivalent on August 17, 1999 (reference K991980) and the Mammotome® Hand Held 8 Gauge Probe that was determined to be substantially equivalent on January 18, 2001 (reference K003297).

The Sanarus Core Tissue Biopsy System has similar indications for use and technological characteristics as the predicate devices. The patient contact components and component materials for obtaining core biopsy samples in both the new and predicate devices are equivalent. The packaging materials, packaging configurations, sterilization methods and sterility assurance level are also equivalent.

Based on the indications for use, technological characteristics and testing results, the Sanarus Core Tissue Biopsy System does not raise significant new questions of safety and effectiveness.

(8) Performance Data Summary

Testing confirms that the quality of samples obtained with the Sanarus Core Tissue Biopsy System is equivalent to the predicate devices and that the use of a cooled probe to engage the tissue does not affect the histological evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Vincent Cutarelli
Senior Vice President, Regulatory Affairs
and Quality Assurance
Endocare, Inc.
7 Studebaker
Irvine, California 92618

Re: K003528
Trade/Device Name: Sanarus Core Tissue Biopsy System
Regulation Number: 876.1075
Regulatory Class: II
Product Code: KNW
Dated: February 1, 2001
Received: February 5, 2001

Dear Mr. Cutarelli:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number: K003528

Device Name: Sanarus Core Tissue Biopsy System

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Concurrence of CDRH, Office of Device Evaluation (ODE):

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K03528

Prescription Use: X
(Per 21 CFR 801.109)